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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|----------------------------|----------------------|---------------------|------------------|
| 10/809,831 | 03/26/2004 | Thomas R. Kozel | 031673-003000 | 7955 |
| 22204 NIXON PEABO | 7590 04/08/200 ODY, LLP | EXAMINER | | |
| 401 9TH STRE | | SWARTZ, RODNEY P | | |
| SUITE 900 WASHINGTOI | N, DC 20004-2128 | ART UNIT | PAPER NUMBER | |
| | | | 1645 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 04/08/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | | Appli | Application No. | | Applicant(s) | | |
|---|---|---|---|---|---------------|--|--|
| | | 10/80 | 9,831 | KOZEL ET AL. | | | |
| | | Exam | iner | Art Unit | | | |
| | | Rodne | ey P. Swartz, Ph.D. | 1645 | | | |
| The MA Period for Reply | LING DATE of this commu | nication appears or | n the cover sheet v | vith the correspondence | address | | |
| A SHORTENEI WHICHEVER I - Extensions of time after SIX (6) MON - If NO period for rej - Failure to reply wit Any reply received | D STATUTORY PERIOD IN SLONGER, FROM THE IN may be available under the provision ITHS from the mailing date of this comply is specified above, the maximum shin the set or extended period for repleted by the Office later than three months and adjustment. See 37 CFR 1.704(b). | MAILING DATE OF s of 37 CFR 1.136(a). In a munication. tatutory period will apply a y will, by statute, cause the | THIS COMMUN no event, however, may a and will expire SIX (6) MC e application to become A | ICATION. It reply be timely filed DINTHS from the mailing date of this ABANDONED (35 U.S.C. § 133). | | | |
| Status | | | | | | | |
| 2a)⊠ This action 3)□ Since this | ive to communication(s) filon is FINAL . Is application is in condition accordance with the pract | 2b)∏ This action for allowance exc | is non-final. cept for formal ma | • | the merits is | | |
| Disposition of Cla | ims | | | | | | |
| 4) Claim(s) 15-19,33,35-37,39-49 and 51-60 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 15-19,33,35-37,39-49 and 51-60 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Application Paper | 's | | | | | | |
| 10) The draw Applicant Replacem | fication is objected to by thing(s) filed on is/are may not request that any objected to drawing sheet(s) including or declaration is objected to | : a) ☐ accepted cection to the drawing g the correction is re | (s) be held in abeya quired if the drawin | ance. See 37 CFR 1.85(a) g(s) is objected to. See 37 | CFR 1.121(d). | | |
| Priority under 35 | U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 2) D Notice of Draftsp | nces Cited (PTO-892) erson's Patent Drawing Review (osure Statement(s) (PTO/SB/08) Date | PTO-948) | Paper No | Summary (PTO-413) o(s)/Mail Date Informal Patent Application | | | |

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DETAILED ACTION

1. Applicants' Response to Office Action, received 28 January 2009, is acknowledged.

Claims 15, 33, 40 and 51 have been amended.

2. Claims 15-19, 33, 35-37, 39-49 and 51-60 are pending and under consideration.

Rejections Maintained

3. The rejection of claims 15-19, 33, 35-37, 39-49, and 51-60 under 35 U.S.C. 112, second paragraph, as being indefinite for discrimination between infected and non-infected subjects, is maintained.

Applicants argue that the amendment of the claims obviate the rejection because the claims recite that a bacterial infection by a PGA-producing pathogen is indicated if the detected level exceeds the reference level.

The examiner has considered applicants' argument in light of the amendments, but does not find it completely persuasive. While the amended claims do recite "wherein bacterial infection by a PGA-producing pathogen in said vertebrate is indicated if the level of soluble PGA is greater than the reference value", there is no actual recitation of the source of the reference value nor what is the reference level. Thus, if one obtains a level of soluble PGA in a biological sample, it remains unclear how one discriminates between infected and non-infected subjects without have a specific reference value to utilize as a cutoff level, and the identity of the source of said specific reference value.

Conclusion

- 4. No claims are allowed.
- 5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

March 30, 2009